

Washington Watch

Nanosilver Pesticide Products: What Does the Future Hold?

The FIFRA SAP report raises important questions

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Last issue's installment of the "Washington Watch" column discussed some key issues surrounding nanosilver and noted an ongoing review by the U.S. Environmental Protection Agency (US EPA) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP). Now that the SAP has issued its much-anticipated report and recommendations, it is worth revisiting the topic of nanosilver pesticides.

Nanomaterials: The Importance of FIFRA

Much has been written about nanomaterials and US EPA's regulation of them under the Toxic Substances Control Act. Less has been written about the Agency's regulation of nanopesticides under FIFRA, even though the subject is every bit as significant, evolving, and precedent-setting.

Earlier this year, the FIFRA Scientific Advisory Panel released the minutes of its November 3-5, 2009, meeting regarding evaluation of the potential hazard and exposure associated with nanosilver and other nanometal pesticide products. The minutes provide the SAP's in-depth recommendations in response to public comments and testimony received on the questions put to the panel by US EPA and reflect the deliberations of the SAP members in response to those questions.

This column offers background on nanosilver pesticides and the issues surrounding them, explains why US EPA decided to convene the FIFRA SAP on nanosilver, summarizes key aspects of the SAP recommendations, and discusses the implications of the SAP's recommendations for future pesticide registration of nanomaterials.

The Nanosilver Battleground

Perhaps due in part to the many silver pesticide registrations currently in effect and the broad commercial success of "nanosilver" as a product ingredient, nanoscale silver has become the battleground on which environmental and consumer groups, pesticide manufacturers, and US EPA may wage the first nanopesticide registration battle.

Silver has long been recognized for its antimicrobial properties. In nanoscale form, it is unquestionably the most widely discussed and debated "nanopesticide." Silver is a well-studied biocide with, as its supporters note, "an established record of safe use."

Registrants of nanosilver-containing products are quick to remind US EPA and other stakeholders that nanosilver particles have been used (and registered under FIFRA) for decades. Thus, the argument goes, they cannot be considered "new" for FIFRA registration purposes -- and, by implication, should not be subject to additional FIFRA testing requirements because of their particle size.

Benefits of Nanopesticides

US EPA's Office of Pesticide Programs (OPP) recognizes the benefits of nanopesticides, especially for agriculture and food production. Among the many promising agricultural and biocidal applications of nanotechnologies are nanosensing devices, which offer the promise of real-time pathogen detection and location reporting using nanotechnologies in micro-electromechanical system technology.

The increased biological efficiency of certain nanopesticides could allow for diminished applications of conventional pesticides. Similarly, nanodevices used for "smart" treatment delivery systems hold promise. Smart field systems detect, locate, and report on pathogens, then apply pesticides and fertilizers as needed prior to the onset of symptoms.

Nanopesticide delivery systems (including nanocapsules, nanocontainers, and nanocages) could replace conventional emulsifiable concentrates, thus reducing the organic solvent content in agricultural formulations and enhancing the dispersity, wettability, and penetration strength of the droplets. Enhanced use of smart systems could also diminish runoff and avert the unwanted environmental movement of pesticides.

These are only a few of the innovations that nanopesticides can offer. US EPA also observes that "[f]ertilizers and pesticides that incorporate nanotechnology may result in less agricultural and lawn/garden runoff of nitrogen, phosphorous, and toxic substances, which is potentially an important emerging application for nanotechnolog[ies] that can contribute to sustainability."¹

OPP and the Nanotechnology Workgroup

In 2006, OPP formed a Nanotechnology Workgroup to develop a regulatory framework for nanopesticides. Through this workgroup, OPP has been working with other US EPA program offices to consider how best to address the growing number of issues posed by nanoscale pesticide materials, including inert ingredients.

US EPA regulates pesticides pursuant to the authority granted by FIFRA. The *Nanotechnology White Paper* issued by the Agency's Science Policy Council includes a brief discussion of FIFRA, noting US EPA's expectation that "[p]esticide products containing nanomaterials will be subject to FIFRA's review and registration requirements."²

Discussed below are several key issues on which OPP is working with respect to nanoscale pesticide products.

Registration Issues

There are a number of issues related to FIFRA registration, including the following:

- How will OPP review and approve a new nanopesticide?
- Will OPP consider a nanoscale version of a conventional pesticide to be a new pesticide?
- What will inform OPP's registration decision logic?
- What are OPP's data needs with respect to nanopesticides, and how will they be satisfied given the fact that test protocols and/or methods do not in all cases exist?

Where will the resources come from to undertake this work?

The inclusion of nanoscale materials as inert ingredients in pesticide formulations also raises vexing issues. It is not clear what the review process will be for a new inert and/or a nanoscale version of an existing inert ingredient, what data requirements might apply, and what process OPP will use to review these issues.

Label Claims

- How will US EPA approach the growing number of claims being made by product manufacturers regarding the antimicrobial properties of certain nanoscale substances (e.g., silver nanoparticles)?
- How will the Agency monitor such claims?

Reporting Implications

As discussed below, US EPA is considering revising its FIFRA section 6(a)(2) policy to compel reporting if any component of a pesticide is believed to contain a nanomaterial. This potentially will raise issues for the regulated community. Will the existing guidelines under FIFRA section 6(a)(2) and the requirements set forth in the corresponding regulations be adequate to inform the regulated community's understanding of what US EPA believes to be reportable under FIFRA with respect to nanoscale materials in pesticide products?

Pesticide or Device? A Prior Nanosilver Decision

Even before the decision to convene a FIFRA Scientific Advisory Panel, US EPA had occasion to consider nanosilver. In 2005, OPP considered whether a washing machine that produces silver ions to kill germs is a "pesticide" or a "device" -- a distinction that has important regulatory implications under FIFRA.

Pursuant to FIFRA, US EPA has authority to regulate a product as a pesticide when the product's manufacturer makes claims about its ability to kill pests, including germs. FIFRA specifies that "devices" do not require registration, however.

The washing machine at issue in the 2005 case used silver electrodes to produce ions. The Agency originally advised the manufacturer that the washing machine was a device rather than a pesticide. US EPA based this initial decision on a 1976 determination in which the Agency distinguished between an article that uses physical or mechanical means to trap, destroy, repel, or mitigate pests and an article that incorporates a substance or mixture of substances to prevent, destroy, repel, or mitigate pests. In the 1976 decision, US EPA determined that the former type of article was a device, while the latter was a pesticide, based on statutory definitions of "device" and "pesticide."³

In 2007, however, US EPA announced a "clarification" of its prior interpretation. This time, the Agency stated that ion-generating equipment such as the washing machine would in fact require registration as pesticides under FIFRA.⁴

Why the change? In its 2007 notice, the Agency reiterated that "the key distinction between pesticides and devices is whether the pesticidal activity of the article is due to physical or mechanical actions or due to a substance or mixture." US EPA noted, however, that in 1976 it not been "aware of equipment such as the ion generating washing machine."⁵

The 2007 notice made clear that FIFRA registration is now required for “ion generators that incorporate a substance (e.g., silver or copper) in the form of an electrode, and pass a current through the electrode to release ions of that substance for the purpose of preventing, destroying, repelling, or mitigating a pest (e.g., bacteria or algae).” The notice went on to state, “Because these items incorporate a substance or substances that accomplish their pesticidal function, such items are considered pesticides for purposes of FIFRA, and must be registered prior to sale or distribution.”⁶

As this discussion illustrates, US EPA's interpretive approach is constantly evolving. Additional regulatory issues are likely to arise in this area in coming years, especially since many manufacturers of consumer products now tout their products' ability to kill germs and prevent disease and illness. Such claims are becoming increasingly prevalent in our germ-conscious society.

ICTA Petition

Important background on the controversy surrounding nanosilver antimicrobial products can be found in a May 2008 petition submitted by the International Center for Technology Assessment (ICTA) and a coalition of consumer, health, and environmental groups. The petitioners requested, among other actions, that US EPA classify nanosilver as a pesticide, require the registration under FIFRA of nanosilver products, and determine that nanosilver is a new pesticide that requires a new FIFRA pesticide registration.⁷ ICTA also released an inventory of the nanotechnology-based consumer products referenced in the petition.⁸

The ICTA petition contended that nanosilver is “the most commonly used nanomaterial in consumer products and the fastest growing sector of nanomaterial commercialization.”⁹ It further stated that most companies “market their nano-silver products [by] putting emphasis on the nano-silver ingredient, touting its antimicrobial and antibacterial qualities”¹⁰ The petition asserted that “research has mounted to indicate that nano-silver materials pose serious risks to human health and the environment.”¹¹

In support of its petition, the ICTA-led coalition pointed to, among other things, US EPA Region 9's then-recent FIFRA enforcement settlement with a California company, IOGEAR, that had been making antimicrobial claims for the nanosilver coating on computer peripherals it was marketing.¹²

The ICTA petition requested that US EPA take a number of specific actions:

- Clarify that nanosilver and products containing it are pesticides requiring registration under FIFRA.
- Classify nanomaterial pesticides such as nanosilver as new pesticides (i.e., new active ingredients) that require new registrations, with nano-specific toxicity testing and risk assessment.
- Assess the potential human health and environmental risks of nanosilver under FIFRA, the Food Quality Protection Act, the Endangered Species Act, and the National Environmental Policy Act.
- Take immediate action to halt the sale of nanosilver products that have unapproved antimicrobial claims (including the issuance of stop sale, use, or removal orders).

- Fully apply all FIFRA regulations in the event that US EPA registers any nanosilver products.
- Utilize its FIFRA authority to further review the potential human health and environmental impacts of nanosilver (including undertaking either a classification review or a special review); amend the FIFRA regulations to require as part of a registration application the submission of nanomaterial and/or nanosilver-specific data; undertake a registration review of existing bulk silver registrations; regulate nanosilver pesticide devices; and establish a tolerance for nanosilver under the Federal Food, Drug, and Cosmetic Act.¹³

EPA announced receipt of the ICTA petition in a *Federal Register* notice and requested public comment on the petition.¹⁴ Many comments were submitted in response.

Decision to Convene a FIFRA SAP on Nanosilver

In addition to the ICTA petition, there were other factors motivating US EPA's decision to convene a FIFRA SAP. The Agency had already encountered issues involving nanosilver and had begun to develop relatively extensive experience with it. Moreover, OPP was faced with making decisions on four pending applications that sought registration of products containing nanosilver-based active ingredients.

These nanosilver-containing products (in the form of textile additives, polymers, coatings, and/or plastics) would be used to protect treated products from microorganisms or to impart antimicrobial activity to a treated material. They would be used in the same manner as some of the currently registered silver products, including those used as material preservatives and antimicrobial pesticides.

Notably, many of the 110 currently registered silver-based products actually contain colloidal silver with nanosilver particles that range in size from approximately 2 to 50 nanometers -- a fact explicitly noted by the SAP. In the background paper that US EPA prepared on nanosilver for the SAP, the Agency references information suggesting that there are other pesticide products currently in the marketplace that contain nanosilver.¹⁵

According to the Silver Nanotechnology Working Group (SNWG), an industry coalition formed to foster the collection of data on silver nanotechnology, over "50% of all current EPA-registered silver products are in fact based on nanosilver materials."¹⁶ The SNWG has gone so far as to claim that "all EPA registered silver products through to 1994 were nanoscale silver" (emphasis added)¹⁷ and that "the majority of existing registered silver products are nanosilver, including the algacides and water filters that have been in use for decades."¹⁸

Threshold Issue for the FIFRA SAP

US EPA stated in its SAP background paper that the current state of the science does not contain sufficient information to determine definitively whether (and, if so, to what extent) various forms of nanosilver particles may cause toxic effects beyond those attributable to the release of silver ions. In light of this, the threshold question before the SAP related to whether the Agency can make the required safety finding under FIFRA (i.e., that a pesticide product will not cause unreasonable adverse effects on the environment) with respect to the four pending applications for registration of products containing nanosilver-based active ingredients.

According to US EPA, the FIFRA nanosilver registration applicants claim that the mode of action for nanosilver is the same as for conventional silver, in that the release of silver ions is the source of antimicrobial activity. According to the applicants, because the pesticidal mode of action of nanosilver is the same as that of conventionally sized silver, the potential hazards to human health and the environment resulting from the use of nanosilver as a pesticide will therefore be the same as those resulting from the use of conventional silver.

The Agency likened the registrants' argument to the so-called 0-hypothesis,¹⁹ which states that the toxic effects of nanosilver are proportional to the activity of free silver ions released by the nanoparticles. The question for FIFRA regulatory purposes is whether sufficient data and information exist to validate this hypothesis. Answering this question requires a two-step process: (1) determining whether nanosilver particles enter the body; and (2) determining whether nanosilver releases silver ions and to what extent the ions will be absorbed.

According to US EPA, the registration applicants posit that there will be no (or only trivial) levels of human exposure to nanosilver particles because these particles will not leach from finished products. As a result, any toxic effect to humans would be the result solely of exposure to silver ions. The applicants further argue that, since the effects of exposure to silver are already well understood, no new toxicity testing is necessary.

US EPA expressed several concerns with this argument. First, the Agency noted that the acute toxicity studies routinely submitted with pesticide registration applications do not evaluate the effects of repeated low levels of exposure, and that the only endpoints measured are mortality and clinical signs.

Second, the acute toxicity studies that have been done on nanosilver and nanosilver composites were conducted according to guideline standards intended for conventionally sized antimicrobial pesticides, and "there is no characterization of the test material provided in the study reports."²⁰ Thus, the results may be biased or confounded.

Finally, the Agency expressed concern about exposure to nanosilver among people who handle or apply the nanosilver pesticide products, as well as concern about consumers' exposure to nanoparticles when using the final products as intended.²¹

Questions Posed to the FIFRA SAP

US EPA asked the FIFRA SAP to consider several issues related to nanosilver, including:

- Do pesticide products containing nanosilver as the active ingredient pose potential hazards different from those associated with products containing conventional silver? If so, what do the available data on fate, release, transport, and transformation of nanosilver particles suggest regarding potential exposure to the particles under realistic use scenarios?
- Are the models currently used by the Agency appropriate to predict potential environmental exposures to nanosilver? If not, what modifications would be necessary?
- If the panel believes that nanosilver is different in terms of hazard and exposure, what types of data would US EPA need to consider to assess any potential risks

associated with the use of an antimicrobial pesticide containing nanosilver particles?

- How might information concerning the percentage of particles in a product that fall within the nanoscale range affect the risks posed by the product?
- What types of new information on individual products would be most useful to US EPA in assessing the potential risks posed by antimicrobial pesticides containing nanosilver or nanosilver composites?
- What types of long-term research would be most helpful for improving assessment of the potential risks associated with antimicrobial pesticides containing nanosilver or nanosilver composites?

FIFRA SAP Report

The FIFRA SAP response to US EPA's questions was set out in a report (taking the form of meeting minutes) released on January 26, 2010. The topic of the SAP meeting was officially identified as "Evaluation of the Hazard and Exposure Associated with Nanosilver and Other Nanometal Pesticide Products." In fact, however, the panel's final recommendations addressed nanosilver almost entirely. Little mention was made of "other nanometal pesticide products."²²

The panel's comments and recommendations in the report suggest that formidable challenges may lie ahead for applicants who seek to obtain FIFRA registration for nanosilver pesticides. Some key components of the FIFRA SAP report are highlighted in the sections that follow.

Hazard Profile of Nanosilver

The panel noted that it "was not of aware of any information that suggested that silver ions released from silver nanomaterials would behave differently than silver ions generated by any other source." But the panel "believed that the rate of silver ion production, as well as the distribution of silver in tissue, may differ substantially between silver nanomaterials and other forms of silver."

These and related issues caused the panel to "suggest that the hazard profile of silver nanomaterials may differ from other forms of silver."

Particle Size and Other Properties

The panel "agreed that particle size has a substantial impact on particle properties, including rate and concentration of silver ion release, reactivity and catalytic efficiency, plasmon resonance, and quantum effects." The panel further noted that other "physicochemical properties, such as shape, charge and surface coating, are likely to impact biological response and environmental fate."

Human Exposure to Nanosilver

The panel "agreed that virtually all uses of nanosilver will result in some release of silver, as ionic, nanoparticulate, or composites." Human exposure will likely "occur by inhalation, oral ingestion, and dermal exposure routes and will vary with the product used."

Exposure Modeling

The panel stated that “most existing models are not appropriate for use with silver nanomaterials and will not accurately predict nanosilver exposure scenarios.” The panel suggested that “[n]ew models implementing novel approaches to predict environmental exposures to nanoparticles should be created.”

Toxicokinetics and Toxicodynamics

The panel noted “existing data that suggest differences in toxicokinetics and toxicodynamics for nanoscale materials,” adding that they “strongly believed that in addition to current data requirements under FIFRA, additional assays which compared nanoscale and bulk materials would be most beneficial in addressing” these issues. This conclusion alone may pose significant challenges for nanosilver pesticide applicants.

Environmental Conditions and Nanoparticles

The panel “believed that environmental conditions can affect the properties of nanoparticles, including silver,” noting “literature indicates that ionic strength of water, natural organic matter content and pH affect particle size distribution, dissolution, aggregation rates and fate.”

Data Gaps

The panel “acknowledged that data gaps about potential exposures and hazards related to nanosilver are broad and there is very little information about nanosilver in the environment related to fate, transport and transformation, including what may be released from products or facilities producing nanosilver-enabled products.”

Evaluation of Products Containing Nanoscale Materials

The panel agreed that products containing nanomaterials should be tested on a “case-by-case basis” and that US EPA should use “a meta-analysis on the products to understand trends in life cycle analyses.” The panel also stated that “close attention should be given to products that claim a non-ionic silver mode of action as an antimicrobial agent.”

Research and Information Needs

The panel outlined detailed research recommendations for US EPA to consider with respect to nanosilver, covering areas such as environmental fate and transport, transformation of nanosilver in the environment, and toxicity assessment. This outline, while helpful, may discourage even the most optimistic potential FIFRA registrant of a nanopesticide since the studies needed to meet the identified research needs are likely to be time consuming and very costly.

The panel also identified the following as the “most useful short-term information”:

- Developing a method for assessing nanosilver risk, such as an approach that would classify products into “high/medium/low risk categories.”
- Developing a framework “to determine how physicochemical characteristics of nanomaterials will be integrated to assess risks.”

- Determining the total silver content “in feedstocks, aggregates/mixtures and products containing nanosilver” as an aid to assessing risk.
- Characterizing nanosilver in suppliers’ products.
- Clarifying how the term “nano” should be used and defined, especially with respect to nanosilver. (The panel noted that the common definition of nano is one that involves a size of under 100 nanometers in one dimension and that “poses a unique property.” They noted that, for standardization, “the unique property for nanosilver should be established.”)
- Determining which dose metric should be used to assess exposures.

FIFRA Section 6(a)(2) Policy Change

As noted above, a related (albeit less publicized) development involves US EPA’s plans to announce a new policy under FIFRA section 6(a)(2). This FIFRA section requires pesticide registrants to notify the Agency if “at any time after the registration of [the] pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide.”

Under the new policy, any pesticide registrant who is aware that some constituent of a registered pesticide product is nanosized would have to submit that information to US EPA. In this context, “nanosized” presumably means that the product contains particles or structures with a diameter of less than 100 nanometers.

The Agency is expected to announce this new interpretation of FIFRA section 6(a)(2) reporting requirements through a notice published in the *Federal Register*, either in the form of a pesticide registration notice or as a formal policy statement or regulatory interpretation. This notice is expected to confirm US EPA’s view that substitution of a nanoscale active or inert ingredient for a conventionally sized ingredient in a product currently registered under FIFRA requires that the registrant submit an application to amend the registration.

Concluding Thoughts: High Stakes for Nanotech

The FIFRA SAP is an advisory group whose comments and recommendations US EPA’s Office of Pesticide Programs may accept or reject. At this point, it is impossible to predict which (if any) of the panel’s suggestions on nanosilver will find their way into regulations. Nonetheless, the SAP report offers perhaps the best guidance currently available to nano stakeholders regarding the “state of play” in this important regulatory arena.

Assuming US EPA ultimately concurs with the SAP recommendations -- and concludes that it lacks sufficient data to make the required FIFRA safety finding with respect to nanosilver pesticide products -- many questions will arise as to how the Agency should go about developing a regulatory pathway that will enable the registration of these products. It is by no means clear what tests will be needed, what protocols can or will be used, or how the testing protocols will be validated. Moreover, none of these issues can be sorted out quickly.

Another important issue that remains unclear is how the Agency will ensure that the commercial playing field remains competitive. US EPA acknowledges that many of the 110 currently registered silver-based products actually contain nanosilver. The Agency will

therefore need to consider the difficult question of how to provide fair treatment for both current nanosilver pesticide registrants whose products are already being marketed and applicants whose nanosilver pesticide applications are still pending. As noted last time, the appropriate remedy may well be product-specific and may require a resource-intensive review of the 110 silver-based products already registered as antimicrobial pesticides.

Only one thing is truly clear at this point: Nano stakeholders will be watching the outcome of these issues carefully in the weeks and months to come.

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Notes

¹ Office of the Science Advisor, Science Policy Council, US EPA (2007, February). Nanotechnology white paper at 25. Available online at <http://www.epa.gov/osa/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf>.

² *Ibid.* at 66.

³ 41 Fed. Reg. 51065.

⁴ Environmental Protection Agency (2007, September 21). Pesticide registration; clarification for ion-generating equipment, 72 Fed. Reg. 54039-54041.

⁵ *Ibid.* at 54040. Equipment affected by the 2007 clarification includes, but is not limited to, "washing machines containing electrodes that emit silver, copper, or zinc ions and ion generators used in swimming pools to kill algae and as an adjunct to the chlorination process." US EPA noted that "[o]ther types of technology not listed in this notice could also be affected." This might even include equipment used for disinfection in manufacturing. The Agency requested "information on any other type of equipment that generates ions from electrodes for pesticidal purposes that could be covered under this notice."

⁶ *Ibid.* at 54040.

⁷ International Center for Technology Assessment (2008, May 1). Citizen petition for rulemaking to the United States Environmental Protection Agency. Petition for rulemaking requesting EPA regulate nano-silver products as pesticides. Available online at http://www.icta.org/nanoaction/doc/CTA_nano-silver%20petition_final_5_1_08.pdf

⁸ The inventory is available at <http://www.nanotechproject.org/inventories/consumer/>

⁹ ICTA petition, note 7 above, at 13.

¹⁰ *Ibid.* at 15.

¹¹ *Ibid.* at 16.

¹² *Ibid.* at 25-26. EPA Region 9's press release on the IOGEAR settlement is available online at <http://yosemite.epa.gov/opa/admpress.nsf/2dd7f669225439b78525735900400c31/16a190492f2f25d585257403005c2851!OpenDocument>.

¹³ ICTA petition at 28-30.

¹⁴ Environmental Protection Agency (2008, November 19). Petition for rulemaking requesting EPA regulate nanoscale silver products as pesticides; notice of availability, 73 Fed. Reg. 69644-69646.

¹⁵ OPP FIFRA Scientific Advisory Panel Background Paper: Evaluation of Hazard and

Exposure Associated with Nanosilver and Other Nanometals, (November 3-6, 2009).

¹⁶ Letter from Rosalind Volpe, D.PH., Executive Director, Silver Nanotechnology Working Group, to Steven Bradbury, Ph.D., Acting Director, Office of Pesticide Programs (2010, February 2) at 2. Available online at [http://nanotech.lawbc.com/uploads/file/Nanosilver-SNWG%20Letter%20to%20SAP%20%20\(00056523\).PDF](http://nanotech.lawbc.com/uploads/file/Nanosilver-SNWG%20Letter%20to%20SAP%20%20(00056523).PDF).

¹⁷ Comments of the Silver Nanotechnology Working Group for review by the FIFRA Scientific Advisory Panel (October 30, 2009) at 7. Available online at http://www.silverinstitute.org/images/stories/silver/PDF/epa_hq_opp2009.pdf.

¹⁸ *Ibid.*

¹⁹ See Wijnhoven, S.W.P., Peijnenburg, W.J.G.M., Herberts, C.A., Hagens, W.I., Oomen, A.G., Heugens, E.H.W., Roszek, B., Bisschops, J., Gosens, I., Van De Meent, D., Dekkers, S., De Jong, W.H, van Zijverden, M., Sips, A.J.A.M., & Geertsma, R.E. (2009, June). Nanosilver -- a review of available data and knowledge gaps in human and environmental risk assessment. *Nanotoxicology*, 3(2), 109-138.

²⁰ OPP FIFRA Scientific Advisory Panel Background Paper, note 15 above, at 18.

²¹ *Ibid.* at 13.

²² The SAP report is available online at <http://www.epa.gov/scipoly/sap/meetings/2009/november/110309ameetingminutes.pdf>.